IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Trudee Klautky, et al.

Serial No.: 10/676,568

Filed: September 30, 2003

For: AUTOMATED CYTOLOGICAL SAMPLE CLASSIFICATION

Confirmation No.: 7905

Group Art Unit: 1797

Examiner: Lyle Alexander

APPEAL BRIEF-CFR 41.37

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This Appeal Brief is being filed in furtherance of the Notice of Appeal filed January 31, 2008. It contains the following items in the order indicated below, as required by C.F.R. §41.37:

I. Real Party in Interest
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III. Status of Claims
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V. Summary of Claimed Subject Matter
VI. Grounds of Rejection to be Reviewed on Appeal
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I. Real Party in Interest

The real party in interest in this appeal is Cytyc Corporation of Marlborough, Massachusetts, the assignee of the present application, as evidenced by the

assignment set forth at Reel 014230, Frame 0366. Cytyc Corporation is a wholly owned subsidiary of Hologic, Inc.

II. Related Appeals and Interferences

There are no appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. Status of Claims

This application includes pending claims 1-16 and 18-29, which all stand finally rejected, as noted in the Advisory Action mailed January 4, 2008. Claim 17 is cancelled. The claims on appeal are claims 1-16 and 18-29.

IV. Status of Amendments

All amendments have been entered.

V. Summary of Claimed Subject Matter

Although the claimed invention is not limited to the embodiments described in the specification, the claimed invention will now be described in terms of certain embodiments in order to aid in understanding.

Independent claim 1 is directed to an automated method of classifying a cytological sample that includes providing a cytological sample in solution in a vessel (see, e.g., p. 9, line 13 through p. 11, line 3); optically interrogating the solution with at least one wavelength of light (see, e.g., p. 11, lines 4-26); determining whether a result of said interrogation meets a criterion (see, e.g., p. 11, line 27, through p. 12, line 24); attaching a positive designator to the sample vessel if the result meets the criterion (see, e.g., p. 12, line 27, through p. 13, line 10); and attaching a

manipulation designator to the sample vessel if the result does not meet the criterion (see, e.g., p. 13, lines 11-23).

VI. Grounds of Rejection to be Reviewed on Appeal

A) Whether claims 1-16 and 18-29 are properly rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,258,340 ("Licha").

B) Whether claims 1-16 and 18-29 are properly rejected under 35 U.S.C. § 102(b) as being anticipated by EP 0 573 535 ("Rava").

C) Whether claims 1-16 and 18-29 are properly rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,168,066 ("Zahniser").

VII. Arguments

The Examiner has set forth a rejection of the claims on appeal under 35 U.S.C. § 102(b) over of any of Licha, Rava, or Zahniser. The rejection in view of each reference is discussed separately.

A. Rejection of claims 1-16 and 18-29 under 35 U.S.C. § 102(b) over Licha.

Appellants respectfully submit that claims 1-16 and 18-29 are not properly rejected under 35 U.S.C. § 102(b) over Licha, since Licha does not disclose, expressly or inherently, each and every limitation required by these claims.

Independent claim 1 recites an automated method of classifying a cytological sample, including the act of "providing a cytological sample in solution in a vessel". In contrast, Licha teaches administering compounds to a tissue or an animal *in vivo*. For instance, Licha states:

> This invention relates to *an in-vivo diagnostic method* based on near infrared radiation (NIR radiation) that uses water-soluble dyes and their biomolecule adducts, each having specific photophysical and pharmaco-chemical properties, as a contrast medium for fluorescence and transillumination diagnostics in the NIR range, to new

dyes and pharmaceuticals containing such dyes. (Emphasis provided.) (Column 1, lines 11-19.)

When applying the method according to the invention in in-vivo diagnosis, one or several substances of the general formula I is/are *administered to the tissues, for example, by intravenous injection*, then they are irradiated with light from the visible to the near infrared range of 650 to 1200 nm. Radiation that is not absorbed and fluorescence radiation are recorded separately or simultaneously, or against each other with a delay. A synthetic image is generated from the data obtained. (Emphasis provided.) (Column 8, lines 1-9.)

Licha does not disclose "providing a cytological sample in solution in a vessel", which clearly refers to an *in vitro* process, and nowhere in the record has the Examiner specified where in Licha the act of "providing a cytological sample in solution in a vessel" is supposedly found.

Independent claim 1 further requires "attaching a positive designator to the sample vessel if the result meets the criterion" and "attaching a manipulation designator to the sample vessel if the result does not meet the criterion." The Examiner states (in the third paragraph of page 2 of the Final Rejection mailed November 8, 2007) that these claim limitations may be read on the acts of recording a synthetic image, and subsequent comparison of the image to certain parameters in order to obtain a diagnosis, as taught by Licha. Appellants respectfully submit that this interpretation is contrary to the ordinary language of the claim, especially when properly read in view of Appellants' specification.

As discussed in the specification at page 13, line 24, through page 14, line 3, the designators may be physically or electronically attached to the sample vessel, and such methods for attaching the respective positive and manipulation designators are recited in dependent claims 21-24. In other words, the act of attaching requires a specific physical marking or electronic association *of the vessel* with a respective

positive designator or manipulation designator. Even assuming *arguendo* that the body tissues being imaged in Licha somehow read on the claimed "vessel" (which Appellants respectfully submit is ***not*** a reasonable interpretation), Licha still does not disclose the act of physically or electronically attaching a positive designator or a manipulation designator to these body tissues.

Moreover, since Licha does not teach attaching one of a a positive or manipulation designator to a vessel, it follows that Licha does not teach attaching one of such a designators *after* "determining whether a result of said interrogation meets a criterion", as required by claim 1. In particular, claim 1 recites that a positive designator is attached if the result meets the criterion, and that a manipulation designator is attached if the result does not meet the criterion. This act of "determining whether a result of said interrogation meets a criterion" must occur before the act of "attaching a designator", since it would not be known if a positive designator or a manipulation designator is to be attached until after such determination is made. Nowhere does Licha disclose the act of determining whether a result meets a criterion *before* attaching a positive or a manipulation designator to the body tissues.

Regarding the claim limitation of "attaching a positive designator to the sample vessel if the result meets the criterion" and "attaching a manipulation designator to the sample vessel if the result does not meet the criterion[,]" the Examiner has simply stated (Advisory Action, item 11) that "the Office maintains that these terms are sufficiently broad to have been properly read on Licha" and that "the office has interpreted "positive designator" in its broadest context" (last paragraph of

page 3 of the Final Rejection mailed November 8, 2007. Beyond this unsupported statement, the Examiner has failed to set forth *what* this broad interpretation of the Office is supposed to be, or how Licha meets the "attaching a positive designator" and "attaching a manipulation designator" limitations of claim 1. Appellants respectfully point out that claims must be "given their broadest *reasonable* interpretation *consistent with the specification*" (emphasis added, see MPEP §2111). At a minimum, Appellants are entitled to at least some cogent explanation as to the grounds for making a claim rejection that includes any special interpretation of the claim being applied, how such interpretation is appropriate in view of the specification, and where specifically in the cited reference the limitation, so interpreted, is found.

For at least the foregoing reasons, Appellants respectfully submit that independent claim 1, along with its dependent claims 2-16 and 18-29, are not anticipated by Licha, and request that this rejection be withdrawn.

B. Rejection of claims 1-16 and 18-29 under 35 U.S.C. § 102(b) over Rava.

Appellants respectfully submit that claims 1-16 and 18-29 are not properly rejected under 35 U.S.C. § 102(b) over Rava, since Rava does not disclose, expressly or inherently, each and every limitation required by these claims.

Again, independent method claim 1 recites "providing a cytological sample in solution in a vessel". In contrast, Rava is directed to systems and methods of performing spectral diagnostics to diagnose tissue located in front of a fiber. See, for example, Paragraph 0018 of Rava. Nowhere does Rava describe "providing a

cytological sample in solution in a vessel", nor has the Examiner specified anywhere in the record where in Rava such action is found.

The only instance in the record in which this limitation has been addressed by the Examiner is in the Advisory Action (item 11), where the Examiner states:

> Applicant states Rava…fails to teach the claimed "…sample in solution in a vessel". The instant claim language is sufficiently broad to have been properly read on the instant claims.

Appellants concede that the claims of the present application necessarily read on the claims of the present application, but this circular observation does not set forth any cogent explanation as to where in Rava (as opposed to where in Appellants claims) the limitations of claim 1 are found. Perhaps some other message was intended to be communicated by the Examiner's statement. In any event, the Examiner has not specified where or how Rava teaches the claim limitation of "providing a cytological sample in solution in a vessel."

Independent claim 1 further recites "attaching a positive designator to the sample vessel if the result meets the criterion" and "attaching a manipulation designator to the sample vessel if the result does not meet the criterion." The Examiner states (at the bottom of page 2 to the top of page 3 of the Final Rejection mailed November 8, 2007) that the claimed attachment of respective positive and manipulation designators may be read on the acts disclosed in Rava of recording an image and subsequent comparison to certain parameters to obtain a diagnosis. Appellants respectfully submit that this interpretation is contrary to the specific claim language, especially in view of Appellants' specification. The "recording of an image" described in Rava is not the same as, or equivalent to, physically or

electronically attaching a positive designator or a manipulation designator *to the vessel*.

The Examiner states (in the first full paragraph of p. 4 of the Final Rejection mailed November 8, 2007) that Appellants have argued that Rava "does not teach the claimed attaching a positive or manipulation designator *to the sample*" (emphasis added), and that "the Office maintains these limitations are sufficiently broad to be properly read on Rava as described in the above rejection." Appellants respectfully submit that the Examiner has mis-read the Appellants' arguments and the claim language. To be clear, it is Appellants' stated position in and for the record that Rava does not teach the act of physically or electronically attaching a positive designator or a manipulation designator to a sample vessel, as required by claim 1.

The Examiner alleges (at the bottom of page 2 to the top of page 3 of the Final Rejection mailed November 8, 2007) that the claim limitation of "attaching a positive designator *to the sample*..." (emphasis added) reads on Rava's teaching of recording the image and subsequent comparison, without addressing that the claim calls for alternatively attaching a positive designator or manipulation designator, depending on a result of the interrogation. Appellants are entitled to a cogent explanation as to the grounds for making and sustaining the claim rejections that addresses each and every limitation of the claims, not just some of the limitations.

Since Rava does not teach attaching a positive or manipulation designator to a vessel, it follows that Rava does not teach attaching such a designator *after* the act of "determining whether a result of said interrogation meets a criterion". As discussed above, that the act of "determining whether a result of said interrogation

meets a criterion" in claim 1 must necessarily take place before attaching a positive designator or a manipulation designator to the vessel, since a decision of which designator type (positive or manipulation) to attach is based on whether the interrogation results meet the criterion. These claim limitations are not taught by Rava. Indeed, the Examiner states (at the bottom of page 2 to the top of page 3 of the Final Rejection mailed November 8, 2007) that Rava's comparison to certain parameters to obtain a diagnosis occurs subsequent to recording an image. Thus, nowhere does Rava teach that a step of determining whether a result meets a criterion occurs *before* a step of attaching a designator, even if the act of recording an image could somehow be read on the claimed act of attaching a designator, which Appellants submit is not reasonably the case.

For at least the foregoing reasons, Appellants respectfully submit that independent claim 1, along with its dependent claims 2-16 and 18-29, are not anticipated by Rava, and request that this rejection be withdrawn.

C. Rejection of claims 1-16 and 18-29 under 35 U.S.C. § 102(b) over Zahniser.

Appellants respectfully submit that claims 1-16 and 18-29 are not properly rejected under 35 U.S.C. § 102(b) over Zahniser, since Zahniser does not disclose, expressly or inherently, each and every limitation required by these claims.

In particular, independent claim 1 recites the act of "providing a cytological sample in solution in a vessel". In contrast, Zahniser is directed to methods of staining and imaging cells smeared on a slide. The cells in Zahniser are not provided *in solution in a vessel*. The Examiner argues (second full paragraph on

page 4 of the Final Rejection mailed November 8, 2007) that the claim term "vessel" is sufficiently broad to be properly read on the microscope slide taught by Zahniser. However, nowhere does the Examiner address the recitation of the sample being *in solution* in a vessel and it is not clear whether this limitation is even alleged by the Examiner to be found in Zahniser.

Independent claim 1 further recites the acts of "attaching a positive designator to the sample vessel if the result meets the criterion, and "attaching a manipulation designator to the sample vessel if the result does not meet the criterion[.]" The Examiner states (in the first full paragraph on page 3 of the Final Rejection mailed November 8, 2007) that the claimed attachment of positive and manipulation designators may be read on the acts of recording an image of the slide and subsequent comparison to certain parameters to obtain a diagnosis, as taught by Zahniser. Appellants respectfully submit that this interpretation is contrary to the claim language, especially when properly read in view of Appellants' specification. As discussed above with respect to the respective rejections over Licha and Rava, the recording of an image is not the same as or equivalent to the claim limitation of "attaching a positive or manipulation designator to a vessel".

The Examiner indicates (in the second full paragraph of page 4 of the Final Rejection mailed November 8, 2007) that the microscope slide taught by Zahniser reads on the claimed vessel. But, nowhere does Zahniser teach that a positive or manipulation designator is attached (physically or electronically) to the microscope slide. And since Zahniser does not teach "attaching a designator to the vessel", Zahniser also does not teach "attaching a designator to the vessel" *after*

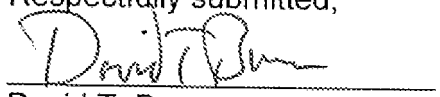
"determining whether a result of said interrogation meets a criterion." As discussed above, claim 1 requires that the act of "determining whether a result of said interrogation meets a criterion" occur before the act of "attaching a designator," since the decision of which designator type (positive or manipulation) to attach to the vessel is based on whether the interrogation results meet the criterion. However, nowhere does Zahniser teach that the act of determining whether a result meets a criterion occurs *before* the act of attaching a designator.

For at least these reasons, Appellants respectfully submit that independent claim 1, along with claims 2-16 and 18-29 depending therefrom, are not anticipated by Zahniser, and request that these rejections be withdrawn.

Conclusion

Based on the above arguments, Appellants respectfully urge the rejected claims are patentable over the cited prior art and may thus be allowed to issue.

Respectfully submitted,



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VIII. Appendix of Claims Involved in the Appeal

1. An automated method of classifying a cytological sample, comprising:

providing a cytological sample in solution in a vessel;

optically interrogating the solution with at least one wavelength of light;

determining whether a result of said interrogation meets a criterion;

attaching a positive designator to the sample vessel if the result meets the criterion; and

attaching a manipulation designator to the sample vessel if the result does not meet the criterion.

2. The method of claim 1, wherein the positive designator designates the sample as satisfactory for performing an assay.

3. The method of claim 2, wherein performance of the assay comprises preparing a specimen slide from said sample.

4. The method of claim 2, wherein the sample meets the criterion if it contains sufficient cells for performing the assay.

5. The method of claim 4, wherein the cells are prokaryotic, eukaryotic, or archea type cells.

6. The method of claim 1, wherein the positive designator indicates that the sample is satisfactory for automated slide preparation.

7. The method of claim 1, wherein the positive designator indicates that the sample is adequate in quantity to allow for withdrawal of a portion of the sample for performing an assay.

8. The method of claim 1, wherein the manipulation designator indicates that acquisition of an additional sample is needed for performing an assay.

9. The method of claim 1, wherein the manipulation designator indicates that treatment of the sample is needed prior to performing an assay.

10. The method of claim 9, wherein the treatment comprises adding acetic acid to the sample.

11. The method of claim 9, wherein the treatment comprises adding a reducing agent to the sample.

12. The method of claim 1, wherein the criterion is a concentration of cells in the sample.

13. The method of claim 1, wherein the criterion is a concentration of cells of a particular type in the sample.

14. The method of claim 13, wherein the cells are endocervical cells.

15. The method of claim 1, wherein the criterion is a level of mucus in the sample.

16. The method of claim 1, wherein the criterion is a level of blood in the sample.

17. Canceled.

18. The method of claim 1, wherein the sample is mixed prior to optically interrogating the solution.

19. The method of claim 18, wherein the mixing is performed manually.

20. The method of claim 18, wherein the mixing is performed automatically.

21. The method of claim 1, wherein the positive designator comprises a marking on the vessel.

22. The method of claim 1, wherein the positive designator comprises a designation in an electronic memory.

23. The method of claim 1, wherein the manipulation designator comprises a marking on the vessel.

24. The method of claim 1, wherein the manipulation designator comprises a designation in an electronic memory.

25. The method of claim 1, wherein the method is performed simultaneously with obtaining the sample from a subject.

26. The method of claim 1, wherein the method is performed in conjunction with obtaining the sample from a subject.

27. The method of claim 7, further comprising preparing a slide from the sample after removing withdrawal of said portion.

28. The method of claim 1, wherein the sample is selected from the group consisting of blood; urine; semen; milk; sputum; mucus; plueral fluid; pelvic fluid; sinovial fluid; ascites fluid; a body cavity wash; eye brushing; skin scrapings; a buccal swab; a vaginal swab; a pap smear; a rectal swab; an aspirate; a needle biopsy; a section of tissue; plasma; serum; spinal fluid; lymph fluid; an external

secretion of the skin, respiratory, intestinal, or genitourinary tract; tears; saliva; a tumor; an organ; a microbial culture; and an in vitro cell culture constituent.

29. The method of claim 1, wherein the sample comprises a water-soluble alcohol in an amount effective to preserve the sterility of the solution toward at least one contaminant.

IX. Evidence Appendix

A. U.S. Patent No. 6,258,340 to Licha, et al; originally cited by the Appellant in the Information Disclosure Statement dated November 17, 2003.

B. European Patent No. 0 573 535 to Rava et al; originally cited by the Appellant in the Information Disclosure Statement dated November 17, 2003.

C. U.S. Patent No. 5,168,066 to Zahniser, et al; originally cited by the Examiner in the Office Action dated June 8, 2007.

X. Related Proceedings Appendix

None.